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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/029,407

12/26/2001

Larry Caldwell

CALD-007

3764

24353

7590

11/18/2002

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EXAMINER

YOUNG, MICAH PAUL

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 11/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/029,407

Applicant(s)

CALDWELL ET AL.

Examiner

Micah-Paul Young

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1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4. 6) ☐ Other: .

DETAILED ACTION

Papers Received

Information Disclosure Statement and Change of Address

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Drizen et al (USPN 5,897,880). The claims are drawn to a method of a method of at least ameliorating headache pain of a mammal by topically applying a nonsalicylate NSAID formulation to the skin.

Drizen et al teaches a topical gel formulation comprising diclofenac, which is applied to patients suffering from head neck and back pain. The gel is applied to the patients skin and the pain is relieved after use. Also the patients report that the headache pain is either gone or less frequent. Though not the main focus of the gel, the composition at least alleviates or prevented headaches in the patients (Test Procedure I-IV). These disclosures render the claims anticipated.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1 – 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liedtke (USPN 5,840,755) in view of Drizen et al (USPN 5,897,880) and Brand (USPN 4,681,897).

Claims 1 – 5 are drawn to a method of ameliorating headache pain in a mammal by applying a topical solution of a nonsalicylate NSAID in the form of a cream or patch. Claims 6 – 10 are drawn to a method of treating a headache in a human subject by applying a topical composition of a cream or patch to the forehead, temple or occipital region of the head. The composition would comprise a nonsalicylate NSAID. Claims 11 – 18 are drawn to a method treating a human subject suffering from a headache comprising applying a nonsalicylate NSAID composition to the forehead, temple or occipital regions of the head. The NSAID is diclofenac, indomethacin, ibuprofen, or ketoprofen. The composition is either in the form of a cream or a patch. Claims 19 – 23 are drawn to a kit comprising the composition of the invention and instructions on how to apply the composition.

Liedtke teaches a method of alleviating headache pain in human subjects by applying a patch to the forehead or temple of a subject in need. The patch comprises topical carriers for

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local anesthetics and analgesics, which alleviated the pain (col. 2, lin. 34 – col. 4, lin. 10; claims 1 and 2). The patch however does not teach the nonsalicylate NSAID of the claimed invention.

As discussed above Drizen teaches a method for alleviating pain using a topical diclofenac formulation. The formulation is applied to the neck and back, and as a result the patients' head pain is alleviated or prevented (Test Procedures I- IV).

Brand teaches a topical NSAID composition for alleviating pain in human subjects. The composition of the example uses ibuprofen yet the reference states that similar results were obtained using various other NSAIDs including diclofenac, indomethacin, and ketoprofen (col. 10, lin. 18 – 24, Example VII).

With regard to the claims drawn to the kit comprising the formulation and instruction as to how to apply it, this kit though not expressly taught in the art, is obvious to any pharmaceutical product brought to market. As seen on any ointment purchasable in any drug store, instructions are either printed directly on the packaging or included in the accompanying box. *See Ben Gay®*.

In view of the prior art one of ordinary skill in the art would have been motivated to use the topical composition of Drizen or Brand in the method of Liedtke. Liedtke teaches that analgesics are used to alleviate headaches in patients in need. Drizen teaches that anti-inflammatory agents, specifically NSAIDS such as diclofenac, can be used in this capacity. Brand teaches that similar results can be obtained from similar NSAIDs such as ibuprofen, ketoprofen, diclofenac, and indomethacin. Liedtke provides the patch system, while the other references provide a lotion (cream) composition. Though since all of the formulations are topical the modification of a topical formulation from a patch to gel, lotion or cream is well

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within the level of ordinary skill in the art. Also within this level would be the sufficient amount of NSAID used in the formulation and the appropriate length of time used in the application.

The public presentation of this combination would come with instructions as to how to use it according to individual patient need. A skilled artisan would have been motivated to substitute the formulations in order to impart anti-inflammatory properties onto the formulation of Liedtke. It would have been obvious to make the substitution of the formulation and combination of teachings with an expected result of a method treating headaches comprising applying a topical NSAID, and a packaging with instructions to do so.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kamishita (USPN 4,670,254) teaches a topical gel comprising diclofenac. Bombardelli (EP 0 574 255) teaches a topical composition for alleviating pain, comprising NSAID.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:30am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703-746-7648 for regular communications and 703-746-7648 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Micah-Paul Young
Examiner
Art Unit 1615

MPY
November 4, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600